

Attorney Docket No.: **KUZ-0022**
Inventors: **Ito et al.**
Serial No.: **10/527,710**
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REMARKS

Claims 1-10 are pending in the instant application.

The Examiner has maintained the rejections of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over the prior art cited previously and the reasons of record.

Arguments submitted by Applicant on October 14, 2008 were found unpersuasive as the Examiner suggests that Tsuruda et al. teaches that if the copolymer base contains less than 10% SIS, then the cohesive strength of the tape is diminished. Further, the Examiner suggests that Tsuruda et al. teaches that a base containing less than 1% PIB will lack adhesive strength. The Examiner thus suggests that there are not unexpected results exemplified in the Table at page 20 of the instant application.

Applicants respectfully traverse the maintained rejections under 35 U.S.C. 103(a) over Chono et al. (U.S. Patent 6,139,866) in view of Tsuruda et al. (CA 2 424 579), Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (U.S. Patent 4,031,894), Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (U.S. Patent 5,750,136), Chono et al. in view of Tsuruda et al. and further in view of Higo et al. (U.S. Patent 5,866,157), and Chono et al. in view of Tsuruda et al. and

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further in view of Zaffaroni (U.S. Patent 3,598,122) and further in view of Kochinke (U.S. Patent 5,350,581) has been maintained.

At the outset, Applicants respectfully disagree with the Examiner that teaching of Tsuruda et al. that a base containing less than 1% PIB will lack adhesive strength is indicative of results exemplified in the Table at page 20 of the instant application not being unexpected. This percentage is actually outside the claimed range shown to be critical to the properties of the instant invention. Accordingly, Applicants maintain that results of Table 1 showing that the claimed range achieves unexpected results relative to the prior art range rebut any prima facie case of obviousness based upon overlapping ranges. See MPEP 2144.05 and *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Further, claims of the instant application are drawn to an adhesive patch for maintaining a long-term drug efficacy of fentanyl.

MPEP 2143.01 and *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) state "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless

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**>the results would have been predictable to one of ordinary skill in the art.

Chono et al., which corresponds to Patent Document 2, JP, A, 10-45570, is distinguished from the present invention at pages 1 and 2 of the instant patent application as this reference describes an ion-pair type adhesive patch. As taught at page 2 of the instant application, ion pair type adhesive patches such as taught by Chono are not suitable for maintaining a long-term drug efficacy of fentanyl exceeding one day.

Secondary references fail to remedy the deficiencies in the primary reference of Chono et al. as these references are also unrelated to long-term drug efficacy of fentanyl.

Instead, Tsuruda et al. (CA 2 424 579) describes an adhesive preparation having a substrate which has undergone a processing for imparting ultraviolet-shielding properties; Urquhart et al. (U.S. Patent 4,031,894) relates to scopolamine administration; Scholz et al. (U.S. Patent 5,750,136) relates to mucosal adhesives; Higo et al. (U.S. Patent 5,866,157) relates to matrix type patches with increased absorbability and reduced skin irritation; and Zaffaroni (U.S. Patent 3,598,122) in view of Kochinke (U.S. Patent 5,350,581) relate to patch size.

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Accordingly, as none of the cited prior art references alone or combination teach or suggest improvements in long term drug efficacy of fentanyl exceeding one day, the cited combinations of references cannot teach or suggest improvements in long term drug efficacy of fentanyl exceeding one day .

Thus, the cited combinations of references are in no way predictive of the results obtained with the instant invention and therefore cannot render obvious the instant claimed invention. See MPEP 2143.01.

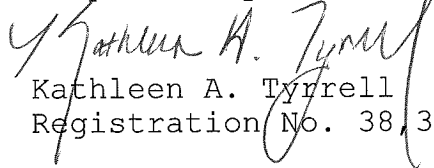
Withdrawal of these rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

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Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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